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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/677,375 | 09/15/2000 | Carl-Martin Bell | 65-99 | 2748 |

23713 7590 12/31/2003

GREENLEE WINNER AND SULLIVAN P C
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/677,375 | BELL ET AL. | |
| | Examiner | Art Unit | |
| | David Lukton | 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 12-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the directives of the directives of the amendment filed 9/25/03, claim 6 has been amended.

Applicants have requested a change in the restriction. No objection is raised thereto; Group 7 is now examined. With respect to the matter of rejoining method claims (20-23) and devices (claims 14-19), this will only take place if all of the limitations of the elected claims (in particular, claim 6) is incorporated into the non-elected claims.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 6-10 are rejected under 35 U.S.C. §103 as being unpatentable over Webber (WO

95/00540).

Webber discloses branched peptides bonded to a solid phase support such as that illustrated in figure 1. Webber does not disclose that the peptides which are formed will be “polydisperse”.

The term “polydisperse” can mean that one has a mixture of a “first” peptide and a “second” peptide, wherein the “first” peptide constitutes 99% is a “monodisperse” peptide (bonded to a solid phase support) and the remaining 1% another “monodisperse” peptide which has a different molecular weight than the “first” peptide, and one less branch point.

This situation is likely to occur during the normal course of synthesis. If one or two of the peptide coupling steps occurs with only 99% conversion, the resulting peptide will be present in the mixture during the next coupling phase. The result will be a mixture in which there is a “second” peptide which differs in molecular weight from the first, and may also have one less branch point. Such a 99:1 ratio of peptides would meet the requirement for “polydispersity”.

There is, apart from the foregoing, another reason why there is polydispersity, and it pertains to semantics more than chemistry. The reason is that the term “solid phase support medium” is completely undefined, and as such is open to broad interpretation. Suppose, for example, that one couples a glycine to a polystyrene resin. Is it the case that the solid phase support that was originally present has lost its property of being such by virtue of

the presence of the glycine? The reality is that, in a functional sense, a polystyrene which bears a glycine is every bit as useful as polystyrene itself as a solid phase support, and certainly polystyrene which bears glycine is far more useful than non-functionalized polystyrene. Consider next figure 1 of the reference. The author has used the term "resin" to indicate one way in which a chemist could characterize the dividing line between a solid phase support and a peptide of interest. But this designation by the authors imposes no prohibition on another chemist who chooses to define "solid phase support" in another way. To a peptide chemist, a "solid phase support" is a physical entity to which one can couple amino acids to make peptides, such that the "solid phase support" will stand up to the reaction conditions. Consistent with this definition, there is no prohibition against a solid phase support containing amino acids. Of course, for the chemist who wants to remove the synthesized peptides from the solid phase support, there would have to be some way of effecting cleavage between the peptide of interest and the solid phase support; a chemist with such an objective might not find such a solid phase support (with amino acids already bonded thereto) especially useful. But in the instant case, there is no such concern.

The objective of the chemist is to retain the peptide on the solid phase support and not cleave it off. Consider again figure 1 of the reference. If the "solid phase support" is just the "resin", then there are 15 branch points. But the reality is that there is no prohibition against the "solid phase support" being the following:

Resin -PPP-QQQ-RRR-Lys(SSS-TTT)₂

The instant claims impose no limitation on the chemical makeup of the “solid phase support”.

The instant claims impose no limitation on the physical properties of the “solid phase support”.

The instant claims impose no limitation on the chemical reactivity of the “solid phase support”.

The instant claims impose no limitation on the number of “degrees of freedom” of any functional group that is present near the surface of the “solid phase support”.

The instant claims impose no limitation on the degree of crosslinking of the solid phase support, or the location of cross linking moieties in the solid phase support.

The instant claims do not preclude the solid phase support from bearing at its surface the following structure: -PPP-QQQ-RRR-Lys(SSS-TTT)₂ .

In accordance with the foregoing, the molecule depicted in figure 1 of the reference is really a mixture of two peptides, one bonded directly to the “resin”, and one which is bonded to the solid phase support which comprises -PPP-QQQ-RRR-Lys(SSS-TTT)₂ .

Accordingly, the claims are rendered obvious.



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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

D. Lukton

12/23/03

DAVID LUKTON
PATENT EXAMINER
GROUP 1600

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